VIII. EFFECTS OF THE FINAL RULE ON SMALL BUSINESSES

In September 1980, Congress enacted the Regulatory Flexibility Act (P.L. 96-354), requiring that regulatory agencies consider the potential effects of regulations on small businesses (SBs). If it is determined that the regulations are likely to affect SBs disproportionately, the Act also mandates that possible relief measures be examined during the rulemaking process.

This chapter focuses on the possible impacts on those small biotechnology businesses that are potentially subject to TSCA. The small business impact analysis is presented first; it investigates the potential economic impact of the rule on SBs. The number of entities in the industry was examined to determine whether a significant proportion of the industry could be considered SBs. The potential impact of regulations on these entities was then reviewed to determine whether SBs may be affected disproportionately. In the second part of this chapter, regulatory flexibility options developed to examine how the disproportionate effects on SBs could be mitigated are presented, and a final assessment of the rule's likely effects on SBs is discussed.

A. Small Business Impact Analysis

In response to the Regulatory Flexibility Act, EPA established specific guidelines for analyzing the potential impact of regulations on small entities. Under the Agency's guidelines, Regulatory Impact Analyses must define "small entity" and determine whether there is "a significant economic impact on a substantial number of small entities" (EPA 1982).

1. Small Business Definition

The Federal definition of "small entities" includes small businesses (SBs), small not-for-profit organizations, and small governmental jurisdictions (EPA 1982). The agency believes that few small not-for-profit

organizations and no small government jurisdictions are likely to be directly affected by the rule.* Therefore, "small entity" has been considered synonymous with small business for this analysis.

The current definition of SB under Section 8(a) of TSCA includes those firms whose annual sales, when combined with the annual sales of their parent company, if applicable, are less than or equal to $40 million, and when less than 100,000 pounds of a regulated chemical is manufactured per site. Firms that generate $4 million or less in annual sales are considered SBs regardless of production volumes (40 CFR 704.3). The Agency, however, believes that the production volume requirement is not relevant to biotechnology because it is unlikely that a company manufacturing biotechnology products would meet the production volume requirement for many of its regulated products (ETD 1988). Therefore, for the purposes of this analysis, SBs are defined as those companies whose annual sales are $40 million or less.

2. Number of Small Businesses

Annual sales information was collected for 72 companies identified in the 1988 ICF Survey as having products potentially subject to TSCA (ICF 1988). This information was obtained from the North Carolina Biotechnology Center (NCBC 1988).** Table VIII-1 shows that of those companies for which specific figures were available, 42 percent had annual sales equal to or below $40 million (22 percent of companies have sales less than or equal to $4 million), while another 41 percent had sales in excess of $500 million. Such a breakdown illustrates how the industry seems to be comprised of small and

* The Agency believes that almost all university research that might lead to reportable releases is taking place at State universities or large private universities.

** See Appendix A for more information on the Survey of Biotechnology companies performed by ICF (ICF 1988).

Table VIII-1. Annual Sales of TSCA-Related Biotechnology Companies: Companies in the ICF 1988 Survey for Which Specific Sales Figures Were Available

Annual Sales[a] ($ million)	Number of Companies	Percentage of Companies[b]
0-1	5	11%
>1-4	5	11%
>4-10	7	16%
>10-20	1	2%
>20-30	1	2%
>30-40	0	0%
>40-500	7	16%
>500	18	41%
Total	44[c]	

NOTE: Fourteen companies simply identified themselves as having less than $40 million.

[a] Annual sales are for the parent company, when applicable.

[b] Percentages may not add to 100 due to rounding.

[c] Seven companies did not submit responses to this question and are not included in the total.

Source: ICF 1988, NCBC 1988.

large companies, with a limited number of intermediate-sized businesses.* None of these large companies, however, is devoted entirely to biotechnology endeavors under the jurisdiction of TSCA. Many have other biotechnology products or are involved in biotechnology only to a very limited extent. Four of the companies with low annual sales, on the other hand, are committed exclusively to biotechnological applications subject to TSCA.

Some companies did not provide specific sales figures but did give an indication of whether their sales were less than/equal to or greater than $40 million. Table VIII-2 includes these additional companies and presents the breakdown between small and large companies (based on the $40 million criterion). This table shows that approximately 50 percent of the biotechnology industry potentially subject to TSCA may be considered SBs. If companies using only non-modified microorganisms (and thus not subject to section 5 PMN reporting) are excluded, then 50 percent (20/39) still would be considered small businesses (ICF 1988) potentially affected by this rule. Thus, SBs comprise a substantial portion of the industry. Because a significant portion of the potentially affected companies are small businesses, the description of the overall regulated community presented in Chapter II may also provide a rough profile of the small business segment. Table VIII-3 presents an alternative means of defining small businesses -- in terms of numbers of employees.

* The biotechnology industry is comprised of a significant number of companies with low annual sales. Annual sales are low because many companies are in the process of developing commercial projects and have not for the most part graduated many R&D projects to the commercial level. For firms that do have commercial projects, sales may be low because of recent commercialization.

Table VIII-2. Size of TSCA-Related Biotechnology Companies, Based on Annual Sales: Companies in the ICF 1988 Survey for Which Sales Ranges Were Available

Size of Company[a]	Number of Companies	Percentage of Companies
Small (Annual Sales ≤$40 million)	33	48%
Large (Annual Sales >$40 million)	35	52%
Total	68[b]	

[a] Annual sales are for the parent company, when applicable.
[b] Four companies, of the 72 that replied to the survey, did not report annual sales.

Sources: ICF 1988, NCBC 1988.

3. The Magnitude of Regulatory Impact on SBs

According to EPA's 1991 Guidelines for Complying with the Regulatory Flexibility Act (OPPE 1991), a significant economic impact would exist if any of the following criteria are met:

- annual compliance costs (i.e., operating, reporting, etc.) exceed 1 percent of sales, or 10 percent of profits for small businesses; and
- debt-financed capital compliance costs for the regulation exceed 20 percent of current cash flow (net income after taxes, plus depreciation) for small businesses.

It was not feasible to definitively establish the impact on SBs of various regulatory options due to limitations in the data and resources available for this analysis. Section B of this chapter presents regulatory options considered to lessen the economic impact of the rule on SBs.

B. Regulatory Flexibility Analysis

In the previous section, it was determined that there are approximately 20 small businesses working with microorganisms in sectors of the biotechnology industry potentially subject to TSCA. Because it was determined that EPA's rule may have imposed a more significant impact on SBs than non-SBs due to limited SB access to resources, the Agency concluded that its Initial Regulatory Flexibility Analysis should identify possible options that would mitigate possible disproportionate effects of the rule on SBs. The following section presents the options considered.

1. Regulatory Alternatives for Small Businesses

In developing possible SB flexibility options, two major issues were considered. First, the flexibility options should not result in an unreasonable risk to human health or the environment as a result of information no longer being available about a specific application or a particular microorganism. Second, flexibility options should reduce

Table VIII-3. Employee Number for TSCA-Related Biotechnology Companies: Data from NCBC for the Companies in the ICF (1988) Survey

Number of Employees[a]	Number of Companies	Percentage of Companies
1- 15	20	29%
16- 25	6	9%
26- 50	7	10%
51- 75	2	3%
76- 100	6	9%
100-1,000	7	10%
>1,000	21	30%
Total	69	

[a] Employee data are for the parent company, when applicable.

Sources: ICF 1988, NCBC 1988.

compliance costs for SBs. In addition, the effects on EPA costs also must be addressed. Two primary flexibility options that could reduce the cost burden of the rule on SBs were considered. The discussions regarding these flexibility options were qualitative because data were not available to analyze thoroughly the total cost-savings under each option.

a. Reduce Up-Front CBI Substantiation Requirements

This option pertained to the substantiation of Confidential Business Information (CBI) under TSCA. The rule contained an option requiring companies to justify their claims of confidentiality for CBI at the time they submitted a TERA. This procedure is known as "up-front CBI substantiation." EPA considered eliminating this requirement for SBs and permitting substantiation at a later time as one way to relieve the potential burden on SBs because it may slightly reduce direct compliance costs for some SB submissions. (Some CBI claims may never require substantiation, while others may have to be substantiated at a later date.) This option also may have slightly reduced filing time of MCAN or TERA submissions by reducing pre-submission paperwork. Risk implications would have been relatively low, arising only from possible delays in making some information available to members of the public who wish to comment. EPA has decided not to require up-front CBI substantiation of CBI claims associated with TERA. Further information on this topic is presented in Section 2.

b. Eliminate Filing Fees

The $100 filing fee for MCAN submissions now required of SBs could be eliminated. The cost savings for companies would be relatively inconsequential; however, it would eliminate one further requirement that potentially could delay the review process if overlooked by the SB. There would be no risk implications, and the cost effects on EPA, from slightly

lower revenues associated with user fees, would be minor. Cost savings to industry, however, would also be minor.

c. Other Possible Flexibility Options

Other regulatory flexibility options have been considered, but were not found appropriate for the reasons given below:

(a) Exempt SBs from prior notification requirements for R&D releases. Require annual reporting instead. This would substantially reduce costs to some SBs. However, it could have significant risk implications since field tests by SBs are likely to be similar to those by large businesses and could result in equivalent risks.

(b) Give SB TERAs priority during EPA review. Although this option would benefit SBs by expediting the review process, there is the potential that the increased burden on EPA of this expedited review would lead to an unacceptable level of risk because adequate review of submissions may not be possible. Also, since much of industry is comprised of SBs, priority setting wouldn't provide much help for most SBs.

(c) Reduce the amount of information required in SB submissions. This would reduce the costs to SBs. However, it could create added risk. The Agency may have to fill the gap by developing this information itself, because adequate information is essential for risk assessment. If the Agency could not develop the proper data, additional risks may be created. If risks could be assessed without certain information, then the question would be raised as to whether even large companies should be required to provide the information.

The primary reasons for eliminating these options are that the increased risks associated with these regulatory relief measures for SBs in certain cases may be significant.

2. Final Assessment of Impacts on Small Business

In developing its final assessment, the Agency relied on information and analysis contained in the Regulatory Impact Analysis (RIA) accompanying the rule and on information submitted by commenters. EPA's reasoning and assessment follow.

In the supporting documentation to the rule, EPA presented its Initial Regulatory Flexibility Analysis (IRFA) as Section VIII of the RIA, and in the preamble to the rule (59 FR 45559/2) requested public comment on the methodology and results of that analysis. Comment received specific to the IRFA suggested that the proposed mechanisms to lessen impacts on small businesses would not be effective where unmodified microorganisms may perform the same function. Other commenters emphasized the potential impacts of the rules on institutions engaged in the development of lower-value products, or products of limited use. One small business asserted that "EPA guidelines for testing genetically engineered microbes" would be associated with prohibitive costs. The Agency also received comment on its alternative regarding up-front substantiation of confidential business information (CBI) claims made in connection with TERA submissions. EPA found addressing the issues raised in these comments to be extremely useful in reaching its final determination on SB concerns.

In considering commenters' concerns for smaller-scale product development and cost impacts, EPA examined the results of its investigation into the potential impacts of the costs associated with regulatory reporting on product development costs and schedules (RIA, Appendix F). In general, the results suggested that larger scale, higher return projects could indeed be less likely to experience substantial impacts; however, one smaller scale project scenario modeled also exhibited financial viability when lower regulatory burdens were considered as part of the product development process. Also, importantly, review duration (termed "delays" in the analysis) played a significant role in the severity of impact sustained by any particular project.

Because smaller scale projects of limited use would most likely be exempt (e.g., organisms used exclusively for research purposes) or involve a relatively limited set of use and exposure scenarios, regulatory costs and delays due to regulatory review would be expected to be non-existent or minimal; thus, the impacts of concern to commenters, which the Agency has interpreted as SB concerns, could be mitigated in many situations of the type described.

With regard to proposed SB relief mechanisms, EPA has decided not to require, from any organization performing field research for commercial purposes, up-front CBI substantiation in connection with TERA submissions, as noted above. While this decision was based on a more general assessment of the implications of up-front substantiation on R&D, rather than the relief it could provide SBs, EPA views the CBI substantiation requirements contained in the rule as providing a potentially significant easing of burden to SBs conducting R&D, depending on how complex and important CBI claims may be to any particular project. Alternatively, EPA has decided not to waive the $100 filing fee for SBs submitting MCANs as this likely would not result in appreciable cost reductions. EPA recognizes this possibility (as noted above); and the absence of supporting views lends support to this presumption.

In reaching its decision to eliminate upfront CBI substantiation for TERA submissions, the Agency considered the fact that most comments indicated upfront substantiation to be overly burdensome for R&D. Though it may be argued that the relief provided by this provision may not be sufficient where unmodified microorganisms are able to perform in a similar fashion, it is not clear that such circumstances will occur with great frequency. Rather, it is more likely that R&D involving modified microorganisms is taking place to improve upon connection with functions found in naturally occurring

microorganisms. It is in connection with these cases that the Agency seeks to reduce regulatory burdens, so as to minimize rule impacts on innovative activity (See chapter VII for more details regarding impacts of these rules on innovative activity).

EPA also emphasizes that other burden minimizing provisions have been included in its rule: the TERA process itself, which streamlines field trials for R&D; and TERA and tiered exemption provisions, which reduce data requirements in connection with more familiar microbiological products.

EPA requested data regarding impacts and product development issues in the preamble to the rule [59 FR 45557/3]; however, no such data were submitted. Nor were specific comments received pertaining to the analysis or cash-flow models presented in the RIA (Appendix F). Therefore, in the absence of such comments, and in light of the flexibility incorporated into the rule, the Agency has determined that impacts of the rule should not hinder industry from pursuing a full range of product applications, nor unduly burden SBs.